FOI release

Freedom of Information request about COVID-19 and vaccines (FOI-21-126)

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This publication is available at https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-15-february-2021/freedom-of-information-request-about-covid-19-and-vaccines-foi-21-126

Thank you for your email.

The authorisation of the Pfizer/BioNTech and the Oxford/AstraZeneca vaccines was done through an expedited rolling review. A ‘rolling review’ can be used to complete the assessment of a promising medicine or vaccine during a public health emergency in the shortest time possible. This is done as the packages of data become available from ongoing studies on a staggered basis. The temporary authorisation under Regulation 174 permits the supply of identified vaccine batches, based on the safety, quality and efficacy data submitted to MHRA. These authorisations do not constitute a marketing authorisation.

All vaccines are tested through three phases of clinical trials to ensure they meet the gold standard. Phase 1 trials are with a small group of people to make sure there are no safety concerns and determines the appropriate dosage for the best immune response. Phase 2 trials are conducted on a larger group of people to check the vaccine works consistently and that the immune response is sufficient. Phase 3 trials test the vaccines on thousands of people for scientists to assess if the vaccine is producing immunity that will prevent disease. Usually, these phases are run in sequence, but in an effort to find a safe and effective Covid-19 vaccine as quickly as possible, once safety has been ascertained through Phase 1, Phases 2 and 3 are being run in parallel. Extensive checks and balances are required at every stage of the development of a vaccine, and this is no different for a Covid-19 vaccine. No stages in the vaccine development processes were bypassed.

Information on the study conducted using the Pfizer/BioNTech vaccine and its results are available in a peer-reviewed journal, the New England Journal of Medicine. A link to this is provided below:

https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=featured_home

The approval for use of the Pfizer/BioNTech and Oxford/AstraZeneca COVID-19 vaccines in the UK followed a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness by the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA expert scientists and clinicians reviewed data from the laboratory pre-clinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine, and also considered the conditions for its safe supply and distribution. The decision was made with advice from the Commission on Human Medicines (CHM), the government’s independent expert scientific advisory body. Regarding the MHRA approval of the Pfizer/BioNTech and the Oxford/AstraZeneca COVID-19 vaccines, further information (including information for physicians and recipients of the vaccine, the vaccine ingredients, and Public Assessment Reports [PARs] for each vaccine) are available on the MHRA website. Links to these are provided below:

https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

Further to the above, the Moderna vaccine has also recently been authorised for use. Further information on this is provided below:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

The MHRA has recently published new advice concerning allergies and the new vaccines: anyone with a previous history of allergic reactions to the ingredients of the vaccine should not receive it, but those with any other allergies can now have the vaccine.

Please look over the updated documents relating to the Pfizer/BioNTech vaccine hosted here: https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

The same documents for the Oxford/AstraZeneca vaccine are hosted here:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

Please see the documents for the Moderna vaccine here:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

The Information for Healthcare Professionals files hosted on the above websites contains a list of the ingredients in each vaccine (section 6.1). Prospective vaccine recipients should share this with their healthcare professional to ensure that they are not allergic to any of these ingredients. Anyone due to receive their vaccine should continue with their appointment and discuss any concerns or medical history of serious allergies with the healthcare professional prior to administration.

I will paste the ingredients below for your convenience:

P/BNT:

This vaccine contains polyethylene glycol/macrogol (PEG) as part of ALC-0159.

ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)

ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide

1,2-Distearoyl-sn-glycero-3-phosphocholine

cholesterol

potassium chloride

potassium dihydrogen phosphate

sodium chloride

disodium hydrogen phosphate dihydrate

sucrose

water for injections

O/AZ:

L-Histidine

L-Histidine hydrochloride monohydrate

Magnesium chloride hexahydrate

Polysorbate 80

Ethanol

Sucrose

Sodium chloride

Disodium edetate dihydrate

Water for injections

Please be aware that the O/AZ vaccine contains GMO and is manufactured in embryonic kidney cells.

Moderna:

This vaccine contains polyethylene glycol/macrogol (PEG) as part of PEG2000-DMG.

The list of excipients is:

Lipid SM-102

Cholesterol

1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)

1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG)

Trometamol (Tris)

Trometamol hydrochloride (Tris HCl)

Acetic acid

Sodium acetate trihydrate

Sucrose

Water for injections

MHRA will be collecting data concerning any adverse reactions observed to vaccine treatment through our Coronavirus Yellow Card site. The MHRA will continue to publish Yellow Card data associated with COVID-19 vaccinations. Yellow Card data for drugs is routinely published on the Yellow Card website, with vaccine data available on request. However, for COVID-19 vaccinations we will be proactively publishing details of adverse drug reactions received, including MHRA assessment of the data to provide context.

Throughout this global pandemic, we have always been guided by the latest scientific advice. Having studied evidence on both the Pfizer/BioNTech and Oxford/AstraZeneca vaccines, the Joint Committee on Vaccination and Immunisation (JCVI) has advised that we should prioritise giving as many people in at-risk groups their first dose, rather than providing two doses in as short a time as possible.

The four UK Chief Medical Officers agree with JCVI that at this stage of the pandemic prioritising the first doses of vaccine for as many people as possible on the priority list will protect the greatest number of at risk people overall in the shortest possible time and will have the greatest impact on reducing mortality, severe disease and hospitalisations and in protecting the NHS and equivalent health services.

This is because the evidence shows that one dose of either vaccine provides a high level of protection from Covid-19.

For both vaccines, data provided to MHRA demonstrate that whilst efficacy is optimised when a second dose is administered both offer considerable protection after a single dose, at least in the short term. For both vaccines the second dose completes the course and is likely to be important for longer term protection.

The NHS across the UK will prioritise giving the first dose of the vaccine to those in the most high-risk groups. Everyone will still receive their second dose and this will be within 12 weeks of their first. The second dose completes the course and is important for longer-term protection.

The JCVI's independent advice is that this approach will maximise the benefits of both vaccines allowing the NHS to help the greatest number of people in the shortest possible time. It will ensure that more at-risk people are able to get meaningful protection from a vaccine in the coming weeks and months, reducing deaths and starting to ease pressure on our NHS.

The following Department of Health and Social Care (DHSC) webpage for the independent report 'Optimising the COVID-19 vaccination programme for maximum short-term impact' from the Joint Committee on Vaccination and Immunisation (JCVI) provides the rationale for the government's implemented dosing strategy:

https://www.gov.uk/government/publications/prioritising-the-first-covid-19-vaccine-dose-jcvi-statement/optimising-the-covid-19-vaccination-programme-for-maximum-short-term-impact

Further, the scientific basis from the JCVI concerning the current evidence on efficacy after single doses of the Pfizer/BioNTech, Oxford/AstraZeneca and Moderna vaccines is available in the public domain and is provided below:

https://www.gov.uk/government/publications/prioritising-the-first-covid-19-vaccine-dose-jcvi-statement

Please note that MHRA can only provide information concerning vaccines that have been authorised for use. For vaccines that have not been authorised MHRA neither confirms nor denies that it holds information falling within the description specified in your request. The duty in Section 1(1)(a) of the Freedom of Information (FOI) Act 2000 does not apply, by virtue of Section 41 (Information provided in confidence) and Section 43 (Commercial interests) of that Act. This should not be taken as an indication that the information you requested is or is not held by the department.

Section 41 is an absolute exemption and no consideration of the public interest is required, except to state that we consider the disclosure of such information to constitute an actionable breach of confidence.

Section 43 is a qualified exemption and a consideration of the public interest should be made. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in publishing this information, which can be used by competitors for their commercial gain. Examples of public interest arguments would be a major public health risk or a major procedural failure or irregularity.

If you have a query about the information provided, please reply to this email.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Due to the ongoing Covid-19 situation, we are not able to accept delivery of any documents or correspondence by post or courier to any of our offices

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Yours sincerely

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

Telephone 0203 080 6000

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